

PEER REVIEW HISTORY

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ARTICLE DETAILS

TITLE (PROVISIONAL)	Reporting of conflicts of interest in oral presentations at medical conferences – a delegate-based prospective observational study
AUTHORS	Grey, Andrew ; Avenell, Alison; Dalbeth, Nicola; Stewart, Fiona; Bolland, Mark

VERSION 1 - REVIEW

REVIEWER	Joel Lexchin York University Canada
REVIEW RETURNED	31-Mar-2017

GENERAL COMMENTS	<p>This manuscript investigates COI statements in oral presentations in five conferences. I regard this investigation as important because statements about COI are easy to make and if even this simple step is not being consistently taken then there are serious questions about the overall management of COI at medical meetings. This is a point that the authors should emphasize in their Discussion. The authors should also point out that a COI declaration was entirely missing in 29% of presentations.</p> <p>Page 5, line 23: Is the figure of 100,000 medical conferences annually an estimate for the entire world?</p> <p>Page 6, line 30: The authors should make it clear that only a single investigator gathered data at each oral session.</p> <p>Page 6, lines 48-50: Was there any effort made to determine if each of the five investigators were equal in their estimate of time?</p> <p>Page 9, lines 12-19: I would suggest that the authors calculate a Kappa score to measure agreement between the oral and written versions of the COI disclosure.</p> <p>Page 9, line 58: Another limitation was that information about each COI declaration was gathered by only a single investigator.</p> <p>Page 11, lines 43-45: Based on what the authors found it doesn't seem as if adequate time was not allocated for speakers but rather that speakers elected not to take enough time.</p>
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REVIEWER	Dr Ray Moynihan Bond University, Centre for Research in Evidence-Based Practice, Australia
REVIEW RETURNED	10-Apr-2017

GENERAL COMMENTS	<p>This is a small well-written and interesting study/paper about an important topic, but with important limitations which are currently underplayed in the manuscript.</p> <p>Apart from a small number of specific suggestions, I think the main object in any revision is to strengthen the limitations section in the paper and abstract, and be more explicit about the study's weaknesses including its limited generalisability.</p> <p>An important caveat to this review is that I am not a bio-statistician, and offer no comment on appropriateness or accuracy of the statistical analysis.</p> <p>Specific comments</p> <p>Article Summary Page 4. Once the limitations section in the Discussion has been revised and expanded, a summary of the limitations should be included in this summary.</p> <p>Page 9 – Line 32. As stated above, I think there is a general need to wind back the asserted generalisability of these results in the Discussion section. For example the line that starts “Our study found...” should add words like “in our sample” after the word conferences. Similarly, Page 9 – line 35: I suggest “were often” (referring to this study) rather than “are often”.</p> <p>Page 9/10– The Limitations section needs to be expanded and strengthened- and I have included several suggestions here – which also need to be reflected in some way in the summary at the start of the article.</p> <p>Page 10- Line 3 I suggest not starting sentence with “Necessarily” --- but words to the effect, “Given the limited nature and simplicity of this study's method...” I think the key limitation is the small sample, which was determined simply by the conferences and sessions which interested the authors. While the authors are explicit about this method, I think they need to be much more explicit about the potential biases this introduces – ie there was no attempt to produce a random or representative sample- and there is a risk in the method used that conferences and sessions were included because there was a suspicion of poor COI disclosure before hand. I think you need to be explicit about the limited generalisability of these results given the nature of the sample. I would also mention that having only 1 assessor in each session is a limitation – rather than having two people independently assess – for example, the assessment of “tone” was very subjective, and not done by two people independently. The statement/issue that appears on page 8 also needs to be mentioned in the limitations section: “Because of the very brief duration of display of most of the COI statements, we were rarely able to accurately count the number of individual COIs disclosed, or to discern their nature or relevance.” I am not clear from the manuscript if there were any pre-specified statistical analyses/calculations – it would be good to state if there were or</p>
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	<p>were not- and if not, mention this in limitations.</p> <p>Context – Page 10 – Line 16 -39...I suggest revising this paragraph, with the limited generalisability of these results in mind, and limiting comments to the conferences in this sample ..rather than assuming generalisability (not withstanding the similar findings from other studies)</p> <p>Figure one could be clearer. For example the line at 2 seconds (or the median) does not stand out very strongly – yet it is a key finding currently lost in this graphic representation.</p>
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REVIEWER	Ricardo Segurado University College Dublin, Ireland
REVIEW RETURNED	29-May-2017

GENERAL COMMENTS	<p>I would consider that this study as it is conducted on presentations by (unwitting) participants, should undergo some ethics scrutiny - I imagine it would be eligible for exemption but as criteria vary by jurisdiction and institution, I wanted to flag it. The methods should at least contain a statement to this effect.</p> <p>The authors conducted a rigorous and simple study, which is a justified, necessary and important piece of work in the meta-research area. I have no criticism of the methodology, statistics used, or the reporting, apart from one minor suggestion - that the readability box-and-whisker plots might be improved by re-scaling the y-axis to a log scale - I will leave it to the authors to judge if this helps.</p> <p>I recommend fleshing out the discussion somewhat.</p> <p>The finding that a whole slide dedicated to a Col statement reduces the amount of time dedicated to it is important, but might be skewed - as the time spent on slides with Col plus additional information may have been entirely dedicated to the additional information rather than the Col. Within the limits of the data that was collected, some discussion is warranted - perhaps as one of the limitations, or recommendation for future work. Similarly, it would be worthwhile in future to study characteristics of the presenter (discipline/background/seniority).</p> <p>I think the result from the UK Continence society also merits further discussion/speculation. They achieve a 72% statement inclusion rate, despite no guidance on this, and despite most of those statements including no disclosure. This is in striking contrast to the other two conferences with no guidance on Col, where statements were rarer, and invariably made only when a disclosure was made.</p>
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	<p>Why might this be?</p> <p>Finally, what are the authors' beliefs on whether COI statements should always be presented? They provide some potentially helpful solutions, but until professional and academic societies, or universities/clinical institutions incorporate such a policy into their charters/constitutions, and enforce them, it is unlikely much progress will be made. This is an opportunity for some pressure to be applied, if the authors feel strongly about it.</p>
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VERSION 1 – AUTHOR RESPONSE

Reviewer: 1

This manuscript investigates COI statements in oral presentations in five conferences. I regard this investigation as important because statements about COI are easy to make and if even this simple step is not being consistently taken then there are serious questions about the overall management of COI at medical meetings. This is a point that the authors should emphasize in their Discussion. The authors should also point out that a COI declaration was entirely missing in 29% of presentations.

Response: Thank you for the supportive comments. We added the following text to the final section of the Discussion, preceding some suggestions for improvement:

‘Our study suggests that management of COI at medical meetings may be suboptimal.’
We strengthened the first sentence of the Discussion to emphasize the prevalence of absent COI statements:

‘In our sample, 29% of oral presentations at medical conferences did not include a COI statement, and therefore did not comply with recommendations that COI disclosure be undertaken in academic discourse’

Page 5, line 23: Is the figure of 100,000 medical conferences annually an estimate for the entire world?

Response: Yes it is, we have clarified this in the revised manuscript.

Page 6, line 30: The authors should make it clear that only a single investigator gathered data at each oral session.

Response: We have added text that makes this clear to the Methods section.

Page 6, lines 48-50: Was there any effort made to determine if each of the five investigators were equal in their estimate of time?

Response: We employed a simple, commonly used method for counting in seconds that does not require the distraction of stopping and starting a timer. We did not test the inter-investigator agreement for this methodology.

Page 9, lines 12-19: I would suggest that the authors calculate a Kappa score to measure agreement between the oral and written versions of the COI disclosure.

Response: Cohen's kappa estimates agreement between ≥ 2 observers of a phenomenon, so we don't think it an appropriate test in this situation. We were only able to determine agreement between the oral and written formats for the presence of a COI statement and for a COI disclosure, not the content of the COI disclosure. We think the current presentation of these data - Results text reporting the absence of a COI statement in the written format for 48% of presentations, and Results text and Figure 3, reporting discordance between the presence of a COI disclosure in 22% of presentations for which there was a COI statement in both oral and written formats – accurately summarizes the data. We haven't altered the manuscript but would be happy to further consider the mode of presentation of the data if the editorial team wishes.

Page 9, line 58: Another limitation was that information about each COI declaration was gathered by only a single investigator.

Response: We have added this limitation to the relevant paragraph in the Discussion.

Page 11, lines 43-45: Based on what the authors found it doesn't seem as if adequate time was not allocated for speakers but rather that speakers elected not to take enough time.

Response: The reviewer is correct. We have deleted the sentence from the text.

Reviewer: 2
General Comments

This is a small well-written and interesting study/paper about an important topic, but with important limitations which are currently underplayed in the manuscript.

Apart from a small number of specific suggestions, I think the main object in any revision is to strengthen the limitations section in the paper and abstract, and be more explicit about the study's weaknesses including its limited generalisability.

An important caveat to this review is that I am not a bio-statistician, and offer no comment on appropriateness or accuracy of the statistical analysis.

Response: Thank you for your comments. We have addressed the specific comments below, including expanding the Limitations section and including a statement about limited generalisability. Whether generalisability is an important limitation is debatable. The most important outcomes [duration of display and explanation of COI], being those affecting the communication to the audience of the nature and relevance of COIs, were similar across the 5 conferences we sampled, and congruent with results from other studies of meeting presentations in single disciplines (orthopedics, oncology, dermatology) different to those we assessed.

Parenthetically, two of us recently attended at the World Conference on Research Integrity, at which only 5 out of >30 oral presentations that we attended included a COI statement. At what point does one accept that an observation applies broadly?

Specific comments

Article Summary

Page 4. Once the limitations section in the Discussion has been revised and expanded, a summary of the limitations should be included in this summary.

Response: We have reworded the summary to strengthen the description of the limitations

Page 9 – Line 32. As stated above, I think there is a general need to wind back the asserted generalisability of these results in the Discussion section. For example the line that starts “Our study found...” should add words like “in our sample” after the word conferences. Similarly, Page 9 – line 35: I suggest “were often” (referring to this study) rather than “are often”.

Response: We have made the suggested wording alterations, and made similar wording changes later in the Discussion.

Page 9/10– The Limitations section needs to be expanded and strengthened- and I have included several suggestions here – which also need to be reflected in some way in the summary at the start of the article.

Page 10 - Line 3 I suggest not starting sentence with “Necessarily” --- but words to the effect, “Given the limited nature and simplicity of this study’s method...” I think the key limitation is the small sample, which was determined simply by the conferences and sessions which interested the authors. While the authors are explicit about this method, I think they need to be much more explicit about the potential biases this introduces – ie there was no attempt to produce a random or representative sample- and there is a risk in the method used that conferences and sessions were included because there was a suspicion of poor COI disclosure before hand.

Response: We adjusted the wording of the Limitations paragraph. We do not think the moderately large sample size to be a key limitation. Sample size is most important in interventional studies when investigating a pre-specified size of effect, a situation which does not apply to our study. Here, the sample size was large enough to provide clear evidence of moderate prevalence of failure to provide a COI statement, and evidence for presentation of COI information that was too brief and/or too poorly described to adequately inform audiences. The sample of presentations we assessed was indeed pragmatically determined – we think this approach most accurately reflects the experience of the vast majority of conference delegates, who will attend conferences and presentations they consider most likely to be of professional value. We had no way of pre-judging the potential for variation in COI disclosure behaviours at sessions attended. We added the limitation that presentations were not randomly selected for assessment.

I think you need to be explicit about the limited generalisability of these results given the nature of the sample. I would also mention that having only 1 assessor in each session is a limitation – rather than having two people independently assess – for example, the assessment of “tone” was very subjective, and not done by two people independently.

Response: We added the limitation about generalising the results to other disciplines, although to our knowledge this is the first study to assess meetings in more than 1 medical discipline. We also added the limitation of having a single assessor, although the main outcomes were objective.

The assessment of tone was, of course, subjective, but it was not a main outcome and we support our assessment by providing verbatim quotes from presenters, so that readers can judge for themselves.

The statement/issue that appears on page 8 also needs to be mentioned in the limitations section: “Because of the very brief duration of display of most of the COI statements, we were rarely able to accurately count the number of individual COIs disclosed, or to discern their nature or relevance.”

Response: That limitation is already mentioned in the relevant paragraph in the Discussion:

'Collecting data.... and a limitation, because it precludes analysis of the nature and relevance of the COI'

I am not clear from the manuscript if there were any pre-specified statistical analyses/calculations – it would be good to state if there were or were not- and if not, mention this in limitations.

Response: The main outcomes, which were pre-specified, are described in the Methods section. Assessment of each involves straightforward descriptive statistics.

Context – Page 10 – Line 16 -39...I suggest revising this paragraph, with the limited generalisability of these results in mind, and limiting comments to the conferences in this sample ..rather than assuming generalisability (not withstanding the similar findings from other studies)

Response: We have reworded the first paragraph of this section in line with the reviewer's suggestions. The second paragraph refers to results from the conferences we analysed. The third paragraph places our work in the context of existing publications, which have reported results congruent with those from our multidisciplinary study.

Figure one could be clearer. For example the line at 2 seconds (or the median) does not stand out very strongly – yet it is a key finding currently lost in this graphic representation.

Response: We have adjusted the box and whiskers plot for the summary ('All') data in Figure 1 such that the median value should be clearly visible.

Reviewer: 3

I would consider that this study as it is conducted on presentations by (unwitting) participants, should undergo some ethics scrutiny - I imagine it would be eligible for exemption but as criteria vary by jurisdiction and institution, I wanted to flag it. The methods should at least contain a statement to this effect.

Response: Thank you for your comments. Please see reply to the Editorial comments. This study is exempt from ethical committee review in our institution.

The authors conducted a rigorous and simple study, which is a justified, necessary and important piece of work in the meta-research area. I have no criticism of the methodology, statistics used, or the reporting, apart from one minor suggestion - that the readability box-and-whisker plots might be improved by re-scaling the y-axis to a log scale - I will leave it to the authors to judge if this helps.

Response: We tried the configuration suggested by the reviewer, but think the current graphical format presents the data more clearly.

I recommend fleshing out the discussion somewhat.

The finding that a whole slide dedicated to a Col statement reduces the amount of time dedicated to it is important, but might be skewed - as the time spent on slides with Col plus additional information may have been entirely dedicated to the additional information rather than the Col. Within the limits of the data that was collected, some discussion is warranted - perhaps as one of the limitations, or recommendation for future work. Similarly, it would be worthwhile in future to study characteristics of

the presenter (discipline/background/seniority).

Response: We added the following sentence to the main findings paragraph in the Discussion:

'The longer duration of display of COI statements when they were presented on slides that contained other information suggests that the other information was responsible for the longer display.'

I think the result from the UK Continence society also merits further discussion/speculation. They achieve a 72% statement inclusion rate, despite no guidance on this, and despite most of those statements including no disclosure. This is in striking contrast to the other two conferences with no guidance on Col, where statements were rarer, and invariably made only when a disclosure was made. Why might this be?

Response: We can only speculate as to why this might be. There has been controversy about the impact of financial COI on the use of transvaginal mesh devices which were associated with adverse patient outcomes. This might have heightened awareness of COI among speakers at the UKCS meeting. An eminent academic in the field, Professor Glazener, University of Aberdeen, suggested this as a possible explanation – we have added this personal communication to the Discussion section of the revised manuscript:

'Among conferences that did not provide instructions about COI statements, the UK Continence Society meeting achieved a higher rate of inclusion of statements. The reason for this is uncertain, but it might reflect heightened awareness of COI arising from controversy about financial conflicts of interest over transvaginal mesh devices (personal communication Emeritus Professor Cathryn Glazener).'

Finally, what are the authors' beliefs on whether Col statements should always be presented? They provide some potentially helpful solutions, but until professional and academic societies, or universities/clinical institutions incorporate such a policy into their charters/constitutions, and enforce them, it is unlikely much progress will be made. This is an opportunity for some pressure to be applied, if the authors feel strongly about it.

Response: We think COI statements should always be presented, and state this view in the concluding paragraph of the Discussion. We agree that academic organisations should apply strategies to ensure compliance with full and adequate COI disclosure, as stated in the same paragraph. We hope the current work and that of others in this area will precipitate improvements in academic behaviour.

VERSION 2 – REVIEW

REVIEWER	Joel Lexchin York University Canada In 2015-2016 Joel Lexchin received payment from two non-profit organizations for being a consultant on a project looking at indication based prescribing and a second looking at which drugs should be distributed free of charge by general practitioners. In 2015 he received payment from a for-profit organization for being on a panel that discussed expanding drug insurance in Canada. He is on the Foundation Board of Health Action International.
REVIEW RETURNED	28-Jun-2017

GENERAL COMMENTS	The revisions undertaken by the authors have addressed my initial concerns.
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REVIEWER	Dr Ray Moynihan Centre for Research in Evidence-Based Practice, Bond University, Australia
REVIEW RETURNED	18-Jul-2017

GENERAL COMMENTS	This re-submission looks good, and I feel the authors have responded to my previous reviewer comments. Thanks for opportunity to review this work. I only have one very tiny comment: On Page 8, line 7, you have 61%, but my calculation is 60% - and in fact - if I am not mistaken - you use 60% in the Table for this same calculation. Would be good to address the discrepancy and perhaps to a final sweep of all the figures.
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